California Health Policy and Data Advisory Commission
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Proposed Minutes
AB 524 Technical Advisory Committee
August 3, 2007

The meeting was called to order by Chairperson Jerry Royer at 10:10 a.m., at the West America Building, 300 Capitol Mall, Room 1560, Sacramento, California. A quorum (defined as 50 percent plus one) was in attendance.

Present:	Absent:
Jerry Royer, MD, MBA, Chair	Marilyn Chow, RN, DNSc
Robert Brook, MD, ScD	Elizabeth Carolyn Abbott
Mark Hlatky, MD	Douglas Bagley, MD
Kathy McCaffrey	Laurie Sobel, JD
William S. Weil, MD	Laura Gardner, MD, MPH
Nancy Donaldson, RN, DNSc	

OSHPD Staff: David M. Carlisle, MD, PhD, Director; Elizabeth Wied, Chief Counsel; Beth Herse, Staff Counsel; Michael Rodrian, Deputy Director, Healthcare Information Division; Joseph Parker, PhD, Manager, Health Quality and Analysis Division; Jonathan Teague, Manager, Healthcare Information Resources Center; Mary Tran, Phd, MPH, Manager, Patient Discharge Data Programs; Holly Hoegh, Manager, Clinical Data Program; Candace Diamond, Manager, Patient Discharge Data Section; Brian Paciotti, Research Program Specialist II

CHPDAC Staff: Kathleen Maestas, Acting Executive Director; Terrence Nolan, Office Manager

Others Present: Vito Genna, CHPDAC Chair; John Lane, MD, University of California, Irvine

Approval of Minutes: Committee Member McCaffrey made a motion to approve the May 15, 2007 Minutes. Committee Member Weil seconded. The minutes were unanimously approved by the Committee.

CHPDAC Chair's Report: Vito Genna, California Health Policy and Data Advisory Commission Chair, reported that the joint TAC/HDPIC meeting and Committees' motions pertaining to adding new data elements to the Patient Discharge Data Set were invaluable to the Commission in determining a final list of data elements to recommend to the Office. Six Commissioners attended the joint meeting and heard the Committee's discussions centered on Dr. Pine's and Dr. Bindman's presentations which enhanced the discussion that took place at the Commission level.

Following the joint meeting, Dr. Parker put together a summary guide prioritized listing of the 23 data elements sent forward by the Committees for further consideration and review. The list also indicated which data elements OSHPD staff felt should not move forward for further study at this point. Staff were hoping that the Commission could help pare down the list keeping in mind that the target would be fifteen and some data elements would possibly drop out in the study and review process.

The Commission settled on 18 data elements and requested that staff provide the Commission with regular progress reports on no less than a quarterly basis. The target for the final review before going to a regulation package would be nine months.

1. Aspartate Transaminase (AST)
2. K (Serum Potassium)
3. NA (Serum Sodium)
4. pH (blood gas)
5. International Normalized Ratio (INR)
6. Albumin
7. Creatinine
8. Blood urea nitrogen
9. Platelets
10. White blood cells
11. Hematocrit/Hemoglobin
14. Pulse/Heart Rate
15. Systolic/Diastolic Blood Pressure
16. Respiration
17. Temperature
18. Oxygen Saturation (by pulse oximetry)
19. Geocoded Address
23. Operating Physician

The Commission removed glucose from the list after extensive debate. There was an impassioned plea made by one Commissioner to leave glucose on as it relates to public health issues such as diabetes and obesity, but the weight of the scientific evidence presented at the joint meeting did not support its inclusion on the list at this time. This does not preclude the consideration of glucose at a future date.

The Commission acknowledged that there will be a great burden on the healthcare facilities because they will be required to buy the software or create programs to accommodate the collection of the additional data elements. The onus is on the Commission and its Committees in advising the Office to act definitively in this matter.

Commissioners also addressed the difficulties in determining definitions and parameters to be used in reviewing the additional data elements, for example, the times that a value is taken; on admission, half an hour later, or an hour later. Normal values also differ for different lab systems and age groups. HDPIC Committee member Ellis, who attended the CHPDAC meeting, stated that the true cost and feasibility of collecting additional data elements could not happen unless the definitions are extremely clear. Currently the OSHPD reporting system is separate for the clinical reporting system and so the additional reporting places a real burden on both systems. The Associations would like to work with OSHPD as they agree with the need for additional data elements in working with risk adjustment.

TAC Committee member Brook took exception to the idea that there should be so much attention paid to the burden placed on healthcare facilities in collection of additional data elements. He stated that collecting data is burdensome, but it is part of understanding how a 2 trillion dollar industry is functioning. "The argument should be that not only is it your responsibility as a hospital to do this, your responsibility as a doctor, this is also part of the reason that you have been given the right to practice medicine."

OSHPD Director's Report: Dr. Carlisle reported that currently there is no State budget in place and none is likely to be in place before August 20th, when the Assembly returns from its vacation.

Healthcare reform is gaining momentum but language supporting the Governor's proposal has not yet been introduced. AB 8, the combination bill from Senator President Pro Tem Parada and Assembly Speaker Nunez, which would establish a pay or play healthcare insurance system in the State of California has been introduced. The Governor's healthcare reform proposal will be showcased across the State once more in the coming weeks via a series of town hall meetings. One salient point in the Governor's proposal is that he is calling for increased reporting and transparency in healthcare. Independent of the Office, there are efforts going forward that will expand data collection and reporting in the State of California.

The recently released CABG (Coronary Artery Bypass Graft) Surgery report is a historic report for the State of California in that it is the first time that outcomes have been reported for individual physicians for a medical condition or procedure. California now joins New York, Pennsylvania, Massachusetts, and New Jersey in reporting this type of surgeon report.

Healthcare Outcomes Center Report: Joseph Parker, PhD

Dr. Parker reported that a draft of the Maternal Outcomes report was produced by UC Davis using 1999-2001 data that was reviewed by staff. Staff has requested a number of revisions from UC Davis. OSHPD wants to insure the data is updated using 2003-2005 data before the public report goes forward. The most probable timeframe for release of the report is 2008.

Holly Hoegh reported that the CCORP Report was released on July 12, 2007. Information highlighted in the Executive Summary included:

- 2003-2004 Hospital results
  - 4 with "Better" Performance Ratings
  - 6 with "Worse" Performance Ratings
- 2003-2004 Surgeon results-overall and by hospital
  - 4 with "Better" Performance Ratings-overall
  - 12 with "Worse" Performance Ratings-overall
- Internal Mammary Artery usage rates by hospital
  - 8 hospitals with low usage rates

The media response included 25 attributed articles in California newspapers, an Associated Press wire story that was picked up by 15+ newspapers and two radio interviews. The media message focused on local surgeon/hospital results and community response as well as the tie-in with healthcare reform and transparency. Additionally, the media expressed concern over possible surgeon avoidance of high-risk patients and surgeon/hospital reputation versus report results.

Committee member Weil asked how the model used in the study addresses the issue of teaching hospitals which by the nature of their function tend to treat more high risk patients.

Dr. Parker stated that the risk adjustment model works well even if the patient is severely ill because the calibration of the model is very good. It is able to predict mortality when a patient dies for low severity cases and also very high severity cases.

Dr. Carlisle added that the idea of avoidance of high-risk patients speaks to a common misconception of the report. Many surgeons that did not participate in the process are reflexively saying that they will avoid older sicker patients, not realizing that the risk adjustment model takes into consideration those parameters. They are also not realizing that if you have a mortality in a lower risk patient versus a higher risk patient, that mortality in a lower risk patient has much more of an impact on their overall rating than a mortality in a higher risk patient.

Patient Discharge Data Validation: Dr. Parker reported on the status of the Patient Discharge Data (PDD) Validation Study which is looking at 4 different primary conditions/procedures:

- Acute myocardial infarction
- Community-acquired pneumonia
- Congestive heart failure
- Percutaneous transluminal coronary angioplasty

The study is focusing on:

- Reliability of all PDD elements (except payer)
- Validity of Condition Present on Admission (CPOA) and Do Not Resuscitate (DNR)
- Audit of 2,250 records from the 2005 data year
- Probability sample from 48 hospitals across California
- Each record reviewed by nurse (validity) and medical record coder (reliability)
- 500 records double reviewed for inter-rater reliability

Each record has been reviewed independently by an RN to determine the validity of the CPOA coding and by a medical records coder to determine the reliability of the codes. The RN's focus is on the whether the condition was really present at admission and that it was coded correctly. The medical records coders are also doing that but they are also reabstracting the entire record so staff has a measure of how well the records have been abstracted comparing our trained coders to hospital staff. Hospitals were notified in May, 2007 and data collection began in June, 2007.

Some early findings of the reliability and validity of coding in the patient discharge data are the OSHPD's definition of DNR does not pick up substantial numbers of "comfort care" orders and DNRs lacking in MD signatures/date.

Staff expects to complete the data collection by late September, 2007 and report back to TAC in early 2008.

Committee member Weil commented that when the Community Acquired Pneumonia study was done, 25 hospitals had a death rate of 7% and 28 hospitals had a 17% death rate, a difference of 10%. Committee member Weil asked if anything was being done to look into what kind of best practices scenarios might be responsible for the difference.

Committee member Donaldson stated that Dr. Carlisle, Joseph Parker and her team had discussed trying to do a small study to look at nurse staffing and data that might explain some variance in patient care. That is something that we had decided to carry forward on the "things to do in the future" list.

Committee member Brook commented that the issue seems to be the way the law is currently written, in that OSHPD is just supposed to be reporting the data and nothing else; nonetheless he encouraged some follow-up to the data reports.

Dr. Parker stated that presently OSHPD does not have the resources to go beyond its mandate.

Committee member Donaldson asked, “why isn’t it possible for OSHPD to develop the capacity that every time the data becomes available, a public/private partnership kicks in and a “best practices” investigation goes into action with a six month timeline to deliver preliminary “best practices” which have been subject to evidence based validation? It is so clear that consumers do not know how to use this data and that we have to give it to them in an actionable way and give physicians the evidence-based processes that are associated with better outcomes.”

Dr. Parker stated that it is very helpful when professional societies step up and say that they will take a look at this data with respect to best practices, but OSHPD does not currently have the resources to engage those societies in investigating “best practices.”

Dr. Carlisle added that there are other efforts looking into quality and transparency that are occurring in California outside of OSHPD. It is the Governor’s intention to enhance quality reporting.

Expanding the Patient Discharge Data: Dr. Parker distributed a copy of the motion passed by the CHPDAC at the June 22, 2007 meeting listing the 18 data elements sent forward for further review and consideration for addition to the Patient Discharge Data:

1. Aspartate Transaminase (AST)
2. K (Serum Potassium)
3. NA (Serum Sodium)
4. pH (blood gas)
5. International Normalized Ratio
6. Albumin
7. Creatinine
8. Blood urea nitrogen
9. Platelets
10. White blood cells
11. Hematocrit/Hemoglobin
12. Pulse/Heart Rate
13. Systolic/Diastolic Blood Pressure
14. Respiration
15. Temperature
16. Oxygen Saturation (by pulse oximetry)
17. Geocoded Address
18. Operating Physician

Committee member Weil questioned the CHPDAC’s decision to leave Creatinine on the list if it already contained BUN. Committee member Weil also

questioned the reasoning behind dropping glucose since patients in hospitals are getting IV's of glucose all the time.

Committee member Donaldson stated that it is here understanding that glycemic control is a major quality of care issue and that poor glycemic control has been associated with higher rates of infection, and a range of other complications the lest of which is length of stay and cost. Committee member Donaldson said, "I proposed it because I know nurses in critical and acute care that focus a great deal on glycemic control."

Dr. Parker explained that it was his understanding that the CHPDAC made its recommendation to take glucose off the list because they thought that as an indicator of public health it could serve a purpose only to hospitalized patients. "Looking at the data presented by Dr. Pine and Associates, it certainly was not one of the most important risk factors for predicting mortality in the groups of patients (cohorts) they looked at.

Committee member Donaldson stated, "It was my recollection that when I asked Dr. Pine directly, he acknowledged that it was in 4 of the models and that he said was pretty powerful." Dr. Parker agreed but stated that Dr. Pine also indicated that glucose appears much less than other data elements.

Chairperson Royer read from the proposed minutes of the June 22, 2007 CHPDAC meeting that directly related to this discussion:

> Commissioner Fine stated that she did not feel that glucose is appropriate. She indicated that she understood that this was an emotional discussion, but that it doesn't relate to the facts of the data determination. It has been scientifically proven that it does relate to quality of care.
>
> Commissioner Brien stated that it does not preclude the collection of glucose, in that it is already being drawn as often part of a routine when a patient comes in, and further tests may be indicated, but a single glucose test, on admission in particular, does not determine whether a patient has diabetes or not, whether a patient has obesity or not, because there are so many factors when a patient comes in pertaining to stress that the glucose level changes.
>
> Commissioner Fine stated that Dr. Pine and Bindman stated that it is so much a part of the normal routine of a hospital that it does not affect quality outcomes. It happens automatically, so that it does not become a separate determinant of quality of care.

Dr. Parker stated that there were about 15 different conditions and procedures and actual complications that Dr. Pine reviewed and with regard to glucose there were four that it was significant in. But in most of the others, for example potassium, it was a significant risk factor across seven of the cohorts, and other

lab values come in at eight, eleven, and nine. Staff was looking for risk factors that were significant predictors in a large number of cohorts.

Dr. Carlisle stated that the selection process was more relativistic than a reflection of the absolute value of any one variable. There was a large number of variables to choose from for the first set of 15 new variables and they are prioritized. The feeling of the CHPDAC was that glucose, in the relative sense would be 18 or 19.

Dr. Parker reported that OSHPD is currently in the "definitions" stage of implementing the CHPDAC's recommendations. Staff is anticipating a phased implementation of data elements collection and will follow up with CHIA and CHA regarding their initial concerns. Dr. Parker stated that he would be making a brief presentation to the CHA Quality Committee on August 8, 2007 explaining where OSHPD is in this process and asking them to react to what has been recommended to the Office. Also, OSHPD wants to assure the hospitals that there will be extensive education and other online materials following any regulatory action, consistent with OSHPD's strong track record of facility training and support.

Hospital Mortality Benchmark Reports: Dr. Parker outlined the four year process involved in producing a traditional OSHPD outcomes report based on administrative data and stated the OSHPD wants to streamline the process. The suggestion for more timely reports is to rely on AHRQ (Agency for Healthcare Research and Quality, and the NQF (National Quality Forum) to identify the conditions and procedures for that merit public reporting. In this way OSHPD avoids the lengthy contract negotiation and model validation steps for the individual reports which will take two years off the timeline. OSHPD would identify these studies as benchmark reports and not as traditional outcomes reports.

There are currently 13 conditions and procedures that AHRQ has suggested from which OSHPD would develop new models. OSHPD would develop the models using the AHRQ Condition Classification System (CCS) to aggregate ICD-9 codes into risk factors (255 potential risk factors). The benchmark reports would be validated with OSHPD's current outcomes reports which has already been done with the CABG report where an ICD-9 based risk model was created that had similar performance characteristics to OSHPD's clinical model.

One critical way in which this method would differ from the traditional reports is that the 98 percent confidence intervals showing that a hospital was better than expected or worse than expected would not be performed. The three-tier grouping of hospitals would not be used as there will be no extensive validation process, instead hospitals will be listed in quintiles.

OSHPD is considering two models that have already been developed and for which OSHPD has record calculated hospital level risk-adjusted mortality rates, abdominal aortic aneurysm repair (AAA) and congestive heart failure (CHF).

Dr. John Lane, MD, Associate Professor, UC Irvine Division of Vascular Surgery, presented background information on AAA stating that it is the sixth leading cause of death in the United States. Congress recognized this by recently passing the Screening Abdominal Aortic Aneurysms Very Efficiently Act (SAAAVE), which will insure that Medicare recipients, 65 and older, entering Medicare with a history of smoking, have a one-time-paid abdominal ultrasound to try to detect AAA so they can be repaired before possible rupture.

The treatment of AAA has changed significantly since the 1990s, with the advent of minimally invasive technology. Traditionally, AAA have been repaired through a standard surgical approach in which the aneurysm is identified, clamped and repaired with a hand-sewn method. The endovascular AAA repair is an offshoot of some of the other percutaneous repairs such as percutaneous coronary intervention iliac stinting. This is performed not through the standard open abdominal exposure but through small femoral incisions or percutanously where a covered stint device is delivered into the abdominal aorta. So, in considering AAA repair, OSHPD would essentially be looking at reporting on two significantly different procedures.

Endovascular AAA repair has been a revolution, in that now it accounts for more than 50 percent of the AAA repairs performed nationwide. Through randomized trials it has been shown that mortalities for endovascular repair are much lower; 1 to 2 percent mortality for AAA repair and 5 to 6 percent morbidity. You can take people who are sicker, older and put them through this type of repair fairly safely. There seems to be no real difference between the two procedures in the greater than five-year survival.

Dr. Carlisle asked which procedure would be used in emergent operations where there is a rupture in process.

Dr. Lane stated that a number of points play a part in the answer. Endovascular AAA repair is still limited by anatomic constraints and not everyone is a candidate for this procedure. Another point is that these devices are very expensive—$12,000—and most hospitals, especially smaller hospitals, can not afford to have an inventory. There is only a subset of patients with ruptured AAA who can be treated endovascularly because of these constraints. It has been reported that in these selected patients, survival for endovascular AAA is better than open repair. In the model being presented only non-ruptured elective AAA repairs are included.

Dr. Parker stated that 245 hospitals performed at least one open or endovascular AAA repair during the 2002-2004 period, the data years being considered. One-third of these hospitals performed more than 30 cases, while many of the remaining hospitals performed fewer repairs. In terms of reporting, the first group will be the focus of the study.

In developing the AAA repair risk model, OSHPD started out by identifying candidate risk factors. There was a literature review followed by an empirical

analysis and review. OSHPD used the AHRQ CCS grouping strategy and hospitalization characteristics to identify potential risk factors. Dr. Lane provided clinical review in terms of risk factor selection. OSHPD wanted to be fairly inclusive by looking at significant associations with mortality.

With respect to chronic conditions, OSHPD found a concordance between what was expected and the CPAA or CPOA coding. For more acute condition, OSHPD found a much larger percentage that were not coded as present of admission but as complications of care.

Initial conclusions from the work done on the AAA risk model:

- AAA risk model shows adequate discrimination and calibration compared to extant clinical/administrative data models from literature
- Sufficient variation is hospital risk-adjusted mortality rates for reporting hospital level outcomes
- Method improves on a publicly reported AAA measure
- Method results in more timely report (16 months)

Committee member Hlatky commented that he thought one of the really valuable parts of any of these reports would be to help people know how many procedures and what outcomes there are at hospitals that they might be considering. But committee member Hlatky stated that he felt a more useful public report would actually state the number of open versus endovascular procedures that a hospital did and how many patients died from each procedure. Stating that experience matters and the current proposed model does not speak to volume outcomes and this should be adequately explored.

Committee member Brook stated that he felt if OSHPD is going to do this report he would suggest a report shows whether a volume outcome relationship exists in the State and how big it is. He also suggested reporting the trend in transformation from open to endovascular and the gross mortality data that pertains because according to the presentation, that is where the greatest variance is. People should be encouraged to get a second opinion when being offered the choice of open and endovascular procedures.

Committee member Donaldson commented that it would be interesting to consider a report produced in non-socio-political that presented implications for consumers. “The notion that physicians are—or hospitals are good with one procedure and are often not good at both should indicate that a person should seek a second opinion.”

Dr. Lane stated that from a consumer perspective, you really want to know the stratified results from those two different procedures and where they perform them well.

Committee member Brook stated that he felt that, “to produce a report that matters, you first have to have some thoughtful discussion of why you remove

an aortic aneurysm electively in the first place and why we're screening for it. We then need to talk about the differences between these two procedures, what we know about short-term and long term mortality and on average benefits to patients of these two procedures." Then OSHPD has to develop the fairest model to explain how risk adjustment was done with our administrative data.

Committee member Brook also suggested using the geocoding of patients to produce a map of California that shows the distribution of volume of the hospitals by locality, so that people could elect to go to a high volume provider if it is shown that we have a volume outcome relationship in either one of these procedures. Committee member Brook felt strongly that this should be a consumer friendly report from the State of California that people can easily use. This should be coupled with an announcement, "since all the professional societies seem to agree with the vascular societies that screening and identifying the appropriate people that need this procedure is life saving.

Analyses of "Do Not Resusictate: Mary Tran, PhD, MPH

Dr. Tran reported that in the early 1990s hospitals requested stronger risk adjustments for OSHPD models. In response, OSHPD added two key data items to the PDD. One was "condition present on admission" and the other was an indicator for "do not resuscitate."

In 2003, OSHPD published the CAP report for the patient years 1999 to 2001, for which DNR was used as a risk factor in the model. The model was run once with DNR and once without, and to be better, a hospital had to be better on both versions of the model. DNR was found to be a strong predictor.

Recently there have been publications reporting that using DNR in a model introduces systematic bias into hospital performance reporting.

The purpose of this presentation was to review the evidence about the use of DNR for California's healthcare quality assessment, specifically whether DNR is an indicator of higher patient acuity and does DNR affect the results of risk-adjusted models.

To do this analysis, OSHPD used two patient data sets for patient cohorts developed for other purpose for which we looked at a correlation between hospital DNR rates with 30-day death rates among their patients that did have DNR orders, and correlation of hospital DNR rates with changes in their quality rating by adding DNR.

This analysis showed that having DNR "yes" in a patient's record does not necessarily mean that that is a very sick patient. In other words, using DNR is not an indicator of how sick the patient is.

Committee member Donaldson commented that is it an indicator of administrative efficiency regarding advanced directives.

CHPDAC Chairperson Genna stated that what he sees on the patient side from long-term care is that DNR is a matter of how chronic the disease is, not about acute episodes and it is certainly not a matter of how sick someone is. An individual may have gone back and forth to hospitals multiple times and has decided to have a DNR sent with them on their next admission. Dr. Tran agreed, stating that in addition to the effect on the kind of treatment they receive, there are cultural differences that come into play with DNR.

Dr. Carlisle commented that he had observed that on average DNR is a severity measure. The problem is that some hospitals are taking more advantage of that effect than others by being much more likely to code DNR on patients that other hospitals were not coded on, and they are getting a greater boost for the DNR variable than the average hospital.

Dr. Tran asked for a recommendation from the committee as to whether the reporting process affects how readily DNR orders are placed in a patients medical records leading to a change in the treatment decisions, with the consequence that totally different reasons are being brought bear on a patients personal decisions about whether to die or not.

Committee member Hlatky stated that he would strongly endorse dropping DNR from predictive models and would go a step further, suggesting that a report be done to increase public awareness of this particular issue.

Committee members McCaffrey, Weil and Donaldson agreed with committee member Hlatky. Committee member Brook stated that he would like to push the hospital industry to explicitly understand what the purpose of their hospital mission is in managing the death process. "I wouldn't give up throwing DNR out until I got agreement from the hospital industry that they could collect that piece of data." Do not use it in models but keep it in the data set. There needs to be an explicit definition of what the purpose of hospitalization is.

Dr. Parker suggested that that could be accomplished by a new definition of a similar data element.

Deputy Director Rodrian stated that he gathered from the committee that OSHPD should begin to aggressively work with the hospital industry to try to come up with a new data element, possibly replace something with a new data element that better reflect what OSHPD is trying to capture, that being severity.

The Committee agreed with Deputy Director Rodrian's assessment of their recommendation.

The meeting adjourned at 1:54 p.m.

The next AB 524 meeting scheduled for November 9, 2007.

Pending:

1. Presentation on the development of a new risk adjusted outcomes model for congestive heart failure to be given at the November AB 524 TAC meeting
2. Status report on POA, patient discharge data, emergency department data and ambulatory surgery data will be given the November AB 524 TAC meeting
3. Demonstration of the Atlas II at a future TAC meeting.